

REMARKS

Status of Claims

Claims 1-40 and 44-54 are pending. Claim 1 is the only independent claim. In this Reply, the claims have been amended to correct their numbering. The claims were originally misnumbered as there were two claims numbered 16. Renumbered claims 46-49 have been amended to replace "H protected with a protective group" with "H provided with a protective group" for consistency. Support for such amendments exists, *inter alia*, in original claim 43. No new matter has been added.

Initially, Applicants would like to thank the Examiner for allowing claims 1-39 (renumbered as claims 1-40).

Applicants respectfully request the Examiner to reconsider and withdraw the rejections in view of the foregoing amendments and the following remarks.

Claim Rejections Under 35 U.S.C. § 112

The rejection of claims 43-53 under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite is respectfully traversed.

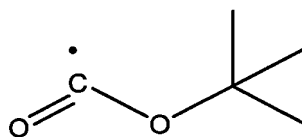
At pages 2-3, the Office Action alleges that phrases involving hydrogen and protective groups are confusing because hydrogen is a monovalent atom. In particular, the Office Action alleges that "it is unclear how any protective groups can be provided for hydrogen or be protecting hydrogen since any additional bonds with hydrogen are not permissible."

Applicants respectfully submit that these phrases are not unclear or indefinite as the *use of protective groups is well known and documented in the art*. In support of this assertion, Applicants submit herewith excerpts from two textbooks directed to protective groups, entitled Greene's Protective Groups in Organic Synthesis ("Greene's") and Protecting Groups.

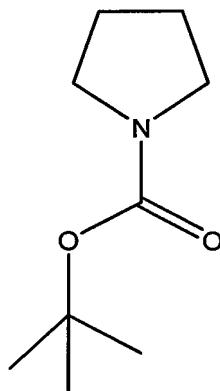
Greene's generally discusses the purpose and mode of operation of protective groups. According to Greene's, "[w]hen a chemical reaction is to be carried out selectively at one reactive site in a multifunctional compound, other reactive sites must be temporarily blocked." Page 1. The protective group reacts with the compound to alter (i.e. block) a reactive site and provide a protected

substrate. The protective group is then removed to regenerate the original functional group of the reactive site. *Id.*

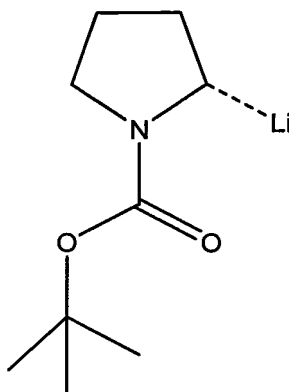
For example, a protective group may block a chemically reactive amino group. Protecting Groups discusses the frequent use of tert-Butoxycarbonyl (Boc) as an amino protective group. Page 505. Boc has the following structure:



As shown in Scheme 8.36, Boc replaces the hydrogen atom in the amino group to provide a protected substrate:



Upon reaction, the Boc group prevents the amino group from reacting. Instead, the following compound forms:



After the desired reaction, the Boc group may be cleaved to regenerate the amino group. Page 506.

Similarly, in the presently claimed process of claim 43, the presently recited protective group can protect an amino group. R⁰¹ and R⁰² attached to the nitrogen atom can form a primary amino group (i.e. when R⁰¹ and R⁰² are both H), a

secondary amino group (i.e. when either R^{01} or R^{02} are H), or a tertiary amino group (i.e. when neither R^{01} nor R^{02} are H). Primary and secondary amino groups are chemically reactive under certain conditions. Thus, the presently claimed process may form undesired by-product. To avoid the undesirable reaction of the primary and secondary amino groups and undesirable formation of by-product, "H provided with a protective group" can be used to prevent the amino groups from reacting.

The meaning of "H provided with a protective group" is perhaps best understood in reference to an example. At page 27, paragraph [0047], the specification explains that the protective groups on H in R^{01} , R^{02} , R^{04} and/or R^{05} can be chosen from alkyl, benzyl or carbamates, for example, or fluorenylmethylchloroformate (Fmoc) groups, benzyloxycarbonyl (Z) groups or tert-butyloxycarbonyl (Boc) groups. Accordingly, the protective group can be Boc, discussed above. Thus, when R^{01} or R^{02} represents "H provided with a protective group" and the protective group is Boc, NR^{01} or NR^{02} is NH converted to its reversible blocked form NBoc.

Accordingly, the presently recited protective groups *do not bond with hydrogen*. Rather, they temporarily replace hydrogen.

Accordingly, the presently claimed process, as defined, would be readily understood by a person skilled in the art. Accordingly, withdrawal of the § 112, second paragraph rejection is respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, the application is respectfully submitted to be in condition for allowance, and prompt, favorable action thereon is earnestly solicited.


If there are any questions relating to this Reply or the application in general, it would be appreciated if the Examiner could telephone the undersigned at (202) 624-2845 so that examination of this application may be expedited.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please

charge any deficiency in fees or credit any overpayments to Deposit Account No.
05-1323 (Docket #029310.53093US).

Respectfully submitted,

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